

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215) 597-4390 Ext:4200 Fax: (215) 597-0875	DATE(S) OF INSPECTION 6/16/2025-6/18/2025 FEI NUMBER 3006761306
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Connie G. Burk, Quality Systems Manager

FIRM NAME DB Biologics, LLC	STREET ADDRESS 2933 N 7th St
CITY, STATE, ZIP CODE, COUNTRY Harrisburg, PA 17110-2109	TYPE ESTABLISHMENT INSPECTED Source Plasma Donor Center

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

The phlebotomy site is not prepared by a method that gives maximum assurance of a sterile container of blood.

Specifically,

On (b) (4) and (b) (4), your firm failed to ensure (b) (4) donor venipuncture sites were prepared in a method to give maximum assurance of sterile blood products. Phlebotomists (b) (6), (b) and (b) (6), (b) were observed preparing the venipuncture sites with (b) (4) and assessing these sites for venipuncture for source plasma collections. However, Phlebotomists (b) (6) and (b) (6) palpated the prepared area (b) (4) and proceeded with the donors' collection procedure.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Michele Gottshall, Investigator	<div style="text-align: right;"> Michele Gottshall Investigator Signed by: MICHELE GOTTSHALL-3 Date signed: 06-18-2025 12:48:23 </div>	DATE ISSUED 6/18/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."